REMARKS

In the office action, claims 19-37 have been objected to, and claims 20-27, 30-33 and 36-38 have been rejected under 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §102.

A restriction requirement has also previously issued in which Applicants' representative verbally elected group I (claims 20-27, 30-33 and 36-38). Applicants hereby confirm the election of Group I.

In response to the office action, Applicants have cancelled claims 19-37, added new claims 38-47, and provide the herein remarks. Reconsideration is respectfully requested.

Claim Objections

In the office action, the claims have been objected to for not being numbered in accordance with 37 C.F.R. 1.126. Applicants thank the Examiner for re-numbering claims 19-37 as 20-38. By this amendment, claims 20-38 have been cancelled and new claims 39-47 have been added. Hence, the objection to the claims has been rendered moot.

§112, Second Paragraph (and §101) Rejections

Claims 20-27, 30-33 and 36-38 have been rejected under §112, second paragraph, as allegedly being indefinite. In particular, claims 20 and 27 have been deemed vague and

indefinite with regards to the terms "fragments thereof," "homologous," and "functionally homologous protein or protein fragment thereof."

In response, and in the interest of moving the application towards allowance, Applicants have added new claims that no longer recite the terms "fragments thereof," and "protein fragment thereof."

However, Applicants submit that the terms "homologous" and "functionally homologous protein" are terms of art. "Homologous" means corresponding or similar in position, value, structure, or function. A "homologous" protein would, for instance, have the same morphology and linear sequence of amino acid residues as another protein.

A "functionally homologous protein," in the context of the application, would be easily understood by a skilled person to mean a protein having the same or similar immunogenic properties as another protein.

Claim 20 has been rejected as being indefinite because it recites using *S. pneumoniae* to treat any microbial infection. In response, claim 20 has been cancelled and corresponding new claim 39 now recites that the claimed composition raises an immune response to streptococcal infections.

Claims 20-27, 30-33 and 36-38 have been rejected as being vague and indefinite for reciting the term "medical preparation." In response, Applicants have cancelled claims 20-

27, 30-33 and 36-38 and added new claims that, at the Examiner's suggestion, recite an "immunogenic composition."

Claims 24 and 26 have been rejected as being vague and indefinite. In response, Applicants have cancelled claims 24 and 26.

Claim 25 has been rejected for being vague and indefinite for reciting the phrase "wherein said protein or said fragment comprises a purified, recombinant or synthetic protein or fragment thereof." In response, Applicants have cancelled claim 25 and added new claim 43 which recites that the protein of claim 39 is a "purified, recombinant or synthetic protein."

Claims 19, 20, 27, 31, 36, 37 and 38 have been rejected for not referring to the sequence by sequence identifier alone. In response, Applicants have cancelled the rejected claims and added new claims that refer to SEQ ID NO:2.

Claims 30, 31, 37 and 38 have been rejected under §112 and §101 as not clearly setting forth active steps. In response, claims 30, 31, 37 and 38 have been cancelled. New claims 39-47, where applicable, recite positive method steps.

Finally, claim 36 has been rejected as being vague and indefinite because only the sequence of SEQ ID NO:1 which encodes the full length protein has been disclosed. Also, the claims is vague due to the term "obtainable." At the Examiner's suggestion, claim 36 has been amended to read "A recombinant protease maturation protein comprising..."

Accordingly, in light of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under §112, second paragraph (and §101).

§112, First Paragraph Rejection

Claims 20-27, 30-33 and 36-38 have been rejected under §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

According to the Examiner, the breadth of the instant claims contains proteins and amino acids sequences other than what is specified in the sequence disclosure.

Firstly, Applicants have cancelled the rejected claims and added new claims that no longer recite "fragments." The term "homologous," as discussed above, in the context of proteins is well known in the art to mean been a protein having the same morphology and linear sequence of amino acid residues as another protein.

Secondly, Applicants would like to point out that because *S. pneumoniae* infections are a major cause of invasive diseases such as meningitis, bacteriemia, and pneumonia, and non-invasive diseases like acute otitis media and sinusitis in children, the development of new vaccines cannot take place in the natural host.

To this end, a model has been developed for the evaluation of vaccine candidates. In this model, described by Alonso Devalasco (Microbiol. Rev 1995:59;591-603), (See page 4,

lines 5-14 of the application) opsonophagocytic activity of antibodies induced by vaccination of rabbits with bacterial antigens is measured.

Said activity is presumed to correlate with *in vivo* protection against *S. pneumoniae*. The protein of claim 39 induced a high opsonophagocytic activity in this test. (See page 4, lines 8-14 of the application). Therefore, the specification enables the protein for use as an immunogenic composition.

On page 6, line 13 of the present application, it is shown that the claimed immunogenic composition is conserved amongst strains of the bacterial species. The results of the opsonophagocytosis test are shown on page 4, lines 10-14, which further prove this.

On page 4, lines 5-14 of the application, it is shown that antibodies were induced by the Pmp, said antibodies showed an opsonophagocyttic activity *in vitro*. A skilled person will easily recognize the correlation of the *in vitro* results of said test with *in vivo* results.

In fact, the Pmp antigen induced such hyperimmune titers that Applicants even consider and claim the use of Pmp as a carrier. See claim 42.

Accordingly, Applicants respectfully submit that the specification gives sufficient guidance for a skilled person to make and use an immunogenic composition comprising Pmp for raising an immune response. In light of the above, Applicants respectfully request that the Examiner reconsider and withdraw the §112, first paragraph, rejections.

§102(b) and §102(e) Rejections

In the office action, claims 20-27, 30-33 and 36-38 have been rejected under §102(b) as being anticipated by WO 98/18930 to Kunsch et al. According to the Examiner, Kunsch et al. teach preventing and attenuating infections caused by *S. pneumoniae* using a vaccine that encompasses a polypeptide or fragment thereof which has 213 identical amino acids to Applicants SEQ ID NO:2.

In response, Applicants have cancelled the rejected claims and added new claims that no longer recite that the protein "comprises" SEQ ID NO:2. New claims 39-47 recite that the "protein has an amino acid sequence in accordance with SEQ ID NO: 2." Kunsch et al. do not disclose SEQ ID NO:2, therefore, Kunsch et al. cannot anticipate the claimed invention.

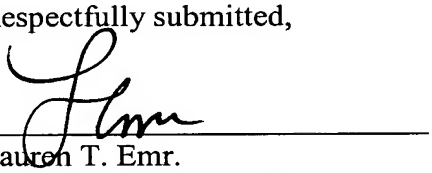
Claims 20-27, 30-33 and 36-38 have been rejected under §102(e) as being anticipated by U.S. Patent No. 6,348,328 B1 to Black et al. According to the Examiner, Black et al. teach a polypeptide which has 48 identical amino acids to Applicants SEQ ID NO:2 and a 97% local similarity.

In response, Applicants have cancelled the rejected claims and added new claims that no longer recite that the protein "comprises" SEQ ID NO:2. New claims 39-47 recite that the "protein has an amino acid sequence in accordance with SEQ ID NO: 2." Black et al. do not disclose SEQ ID NO:2, therefore, Black et al. cannot anticipate the claimed invention.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under §102(b) and (e).

It is now believed that the application is in condition for allowance. Should the Examiner believe any remaining issues can be resolved via telephone, she is cordially invited to contact Applicants attorney at the number provided below.

Respectfully submitted,



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